JAN 2 4 2002

Chapter 1 – Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013899.

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-4041

Contact Person: Marlene A. Shulman

2. **Preparation date**

Date 510(k) prepared: November 20, 2001

3. **Device name**

Trade or Proprietary Name:
VITROS Immunodiagnostic Products Vitamin B12 Assay
VITROS Immunodiagnostic Products Vitamin B12 Calibrators

Common Name: Vitamin B12 assay
Classification Name: Vitamin B12 test system (862.1810)

4. **Predicate device**

The VITROS Immunodiagnostic Products Vitamin B12 Assay is substantially equivalent to the BECKMAN Access Vitamin B12 assay (K933142).

Continued on next page

5. Device description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum and plasma. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products range of immunoassay products (in this case VITROS Immunodiagnostic Products Vitamin B12 Reagent Pack 1/ 2, VITROS Immunodiagnostic Products Vitamin B12/ Folate Reagent Pack 3, Vitros Immunodiagnostic Products Vitamin B12 Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS Vitamin B12 assay.

2. The VITROS Immunodiagnostic System – instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

3. Common reagents used by the VITROS System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).

The VITROS System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

Continued on next page

6. Device intended use

The VITROS Immunodiagnostic Products Vitamin B12 Reagent Pack 1/ 2 and the VITROS Immunodiagnostic Products Vitamin B12/ Folate Reagent Pack 3 quantitatively measures vitamin B12 concentration in human serum and plasma (EDTA or heparin), to aid in the diagnosis of anemia using the VITROS ECi Immunodiagnostic System with Intellicheck.

7. Comparison to predicate device

The VITROS Immunodiagnostic Products Vitamin B12 Assay is substantially equivalent to the BECKMAN Access Vitamin B12 assay (predicate device) which was cleared by the FDA (K933142) for IVD use.

The relationship between the VITROS Vitamin B12 assay and the predicate device, determined by Deming's Regression, is:

VITROS Vitamin B12 assay = 1.028 x X – 9.34 (pg/mL),
with a correlation coefficient of 0.943,
where X is BECKMAN Access Vitamin B12 Assay.

This relationship was determined from a panel of patient samples from a variety of clinical categories.

In addition to the above mentioned correlation study, studies were performed to determine the precision, analytical sensitivity, specificity and expected values of the VITROS Vitamin B12 assay, (refer to the VITROS Vitamin B12 Assay Test Methodology Sheet for summaries of the results of these studies).

Table 1 lists the characteristics of the assays performed using the VITROS Vitamin B12 assay and the BECKMAN Access Vitamin B12 assay.

Continued on next page

7. **Comparison to predicate device,** Continued

Table 1

Device Characteristic	VITROS Vitamin B12 assay	Predicate Device
Calibration range	0-1000 pg/mL	0-1500 pg/mL
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme-labeled
Binding Protein	Porcine Intrinsic Factor-biotinylated intrinsic factor conjugate	Porcine Intrinsic Factor-alkaline phosphotase conjugate
Instrumentation	VITROS Immunodiagnostic System	BECKMAN Access Immunoassay System
Sample type	Serum and plasma (EDTA or heparin).	Serum and plasma (heparin).
Sample volume	30µL	45µL
Incubation time and temperature	48 minutes at 37°C	30 minutes at 36.5 °C

Continued on next page

8. Conclusions

The data presented in the pre-market notification demonstrate that the performance of the VITROS Vitamin B12 assay is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using currently commercially available reagents along with patient samples covering a variety of clinical categories.

The data presented in the premarket notification provide a reasonable assurance that the VITROS Vitamin B12 assay is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Marlene A. Shulman
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
Regulatory Affairs MC00882
100 Indigo Creek Drive
Rochester, NY 14626-5101

JAN 2 4 2002

Re: k013899
Trade/Device Names: Vitros Immunodiagnostic Products Vitamin B_{12} Reagent Pack1/2
Vitros Immunodiagnostic Products VitaminB_{12}/ Folate Reagent Pack 3
Vitros Immunodiagnostic Products Vitamin B_{12} Calibrators
Regulation Number: 21 CFR 862.1810; 21 CFR 862.1810; 21 CFR 862.1150
Regulation Name: Vitamin B_{12} test system; Vitamin B_{12} test system; Calibrator
Regulatory Class: Class II; Class II; Class II
Product Code: CDD; CDD; JIS
Dated: November 21, 2001
Received: November 23, 2001

Dear Ms. Shulman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K013899

Device Name:

1. VITROS Immunodiagnostic Products Vitamin B12 Reagent Pack 1/ 2
2. VITROS Immunodiagnostic Products Vitamin B12/ Folate Reagent Pack 3
3. VITROS Immunodiagnostic Products Vitamin B12 Calibrators

Indications for Use:

1 & 2. The VITROS Immunodiagnostic Products Vitamin B12 Reagent Pack 1/ 2 and the VITROS Immunodiagnostic Products Vitamin B12/ Folate Reagent Pack 3 quantitatively measures vitamin B12 concentration in human serum and plasma (EDTA or heparin), to aid in the diagnosis of anemia using the VITROS ECi Immunodiagnostic System with Intellicheck.

3. The VITROS Immunodiagnostic Products Vitamin B12 Calibrators- for use in the calibration of the *Vitros* Immunodiagnostic System for the quantitative measurement of vitamin B12 in human serum and plasma (EDTA or heparin).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013899

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)